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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,201	01/20/2004	Mark B. Abelson	ORA-001.01	2523
7590 10/04/2004				
Foley Hoag LLP 155 Seaport Blvd. Boston, MA 02210-2600		EXAMINER FAY, ZOHREH A		
		ART UNIT 1614		PAPER NUMBER
DATE MAILED: 10/04/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/762,201	ABELSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Zohreh Fay	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                                    |

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Claims 1-20 are presented for examination.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over The Japanese Abstract 11-5750 and Jonnase et al. (6,274,626).

The Japanese abstract teaches the use of Ketotifen in combination with antihistamine agents such as chlorpheniramine for the treatment of ocular conditions such as conjunctivitis. The use of polymers which are used as artificial tear, such as cellulose and polyvinylpyrrolidone is also taught by the above reference. See the entire abstract. Jonasse et al. Teach the use of pheniramine as an antihistamine being used for treating ocular allergies. See column 3, lines 20-30. The primary reference differs from the claimed invention in the presence of the antihistamine pheniramine. It would have been obvious to a person skilled in the art to add pheniramine to the primary reference, considering that Jonasse et al. teach the use of pheniramine for the treatment of ocular allergy.

One skilled in the art would have been motivated to combine the teachings of the above references, since one relates to the use of ketotifen for the treatment of ocular allergy and the other relates to the use of pheniramine for the treatment of ocular allergy. It is generally considered prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to

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form a composition to be used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As cited by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional antihistamines. It would follow that the recited claims define prima facie obvious subject matter. In re kerkhoven, 626 F. 2d 848, 205 USPQ 1069 (CCPA 1980). The determination of amounts or proportions is considered to be within the skill of the artisan.

Claims 9-16 are rejected under 35 U.S.C. 103 as being unpatentable over Crespo et al. (20020037297). Crespo et al. Teach the use of antazoline and azelastine as an anti-histamine for the treatment of ocular allergy such as conjunctivitis. The use of cellulose derivatives and other polymers, which are known as artificial tear, is also taught by the above reference. See the abstract, page 4, paragraph 1 and page 5, paragraph 3. The above reference differs from the claimed invention in using antazoline and azelastine in combination. It would have been obvious to a person skilled in the art to use the claimed components in combination considering that the prior art teaches each of the components are old and well known antihistamines.

One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of antazoline and azelastine as well known antihistamines. It is generally considered prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition to be used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art.

As cited by the recited teachings, the instant claims define nothing more than the concomitant use of two conventional antihistamines. It would follow that the recited claims define prima facie obvious subject matter. In re kerkhoven, 626 F. 2d 848, 205 USPQ 1069 (CCPA 1980). The determination of amounts or proportions is considered to be within the skill of the artisan.

Claim 17 and 20 are rejected under 35 U.S.C. 103 as being unpatentable over Crespo et al. (200200337297). Crespo et al. Teach the use of azelastine and antazoline as antihistamine agents. The above reference also teaches the use of a short acting antihistamine such as levocabastine and long acting antihistamines such as loratidine. The above reference differs from the claimed invention in the use of azelastine in combination with a short acting antihistamine and antazoline in combination with a long acting antihistamine. It would have been obvious to a person skilled in the art to use the claimed compounds in combination, considering that the prior art teaches the use of each of the individual components as well known antihistamine.

One skilled in the art would have been motivated to employ the teachings of the above reference, since it relates to the use of the claimed components as well known antihistamines. It is generally considered prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a composition to be used for the very same purpose. The idea of combining them flows logically from their having been used individually in the prior art. As cited by the recited teachings, the instant claims define nothing more than the

concomitant use of two conventional antihistamines. It would follow that the recited claims define prima facie obvious subject matter. In re kerkhoven, 626 F. 2d 848, 205 USPQ 1069 (CCPA 1980). The determination of amounts or proportions is considered to be within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

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